K113179

MAY 10 2012

510K Summary

Prepared: May 07, 2012

Submitted by: Quantimetrix Corporation

Establishment Address: Quantimetrix Corporation
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Redondo Beach CA 90278
Phone: 310/536-0006 FAX: 310/536-9977

Establishment Registration Number: 2020715
Contact Person: Kalyna Snylyk, Director of Quality Assurance & Regulatory Affairs
Proprietary Name: Complete D® 25-OH Vitamin D Control
Common Name: Vitamin D Control
Classification Name: Single (Specified) Analyte Controls (Assayed and Unassayed)
Product Code: JJX

Predicate Device:

Fujirebio Diagnostics Vitamin D Control (k110641)

Summary and Principle:

This quality control product is intended to allow an objective measurement of a laboratories performance (procedures and personnel techniques) in comparison to known values. Two clinically relevant levels of controls are available to compare observations with expected ranges therefore assuring consistent performance.

Intended Use:

The Quantimetrix Complete D 25-OH Vitamin D Control is intended for the quality control of laboratory procedures used to quantitate Total 25-OH Vitamin D.

Statement of Substantial Equivalence:

The Quantimetrix Complete D 25-OH Vitamin D Control is intended for the quality control of laboratory procedures used to quantitate Total 25-OH Vitamin D.

The Quantimetrix Complete D 25-OH Vitamin D Control is substantially equivalent to the Fujirebio Diagnostics Vitamin D Control. Both of the devices are quality control serum and are intended for the quality control of laboratory procedures used to quantitate Total 25-OH Vitamin D.

The regulatory submission is prepared pursuant to Title 21 CFR § 862.1660.

A comparison of the features of the Quantimetrix Complete D 25-OH Vitamin D Control and the Fujirebio Diagnostics Vitamin D Control are as follows:

Similarities		
	Predicate Device	New product
Control Name	Fujirebio Diagnositics, Inc.'s Vitamin D Control	Complete D 25-OH Vitamin D Control
Device Type	In vitro diagnostic	In vitro diagnostic
510K Class	1	1
CFR Section	862.1660	862.1660
Product Usage	Clinical and Hospital Laboratories	Clinical and Hospital Laboratories
Intended Use	Fujirebio Diagnostics Vitamin D Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of Vitamin D.	The Quantimetrix Complete D Control is intended for the quality control of laboratory procedures used to quantitate 25-Hydroxyvitamin D
Analyte	25-OH Vitamin D	25-OH Vitamin D
Matrix	Human serum, protein (bovine), purified biochemical materials, and chemicals. Proclin 300 and Gentamicin as preservatives.	Vitamin D depleted human serum, reagent grade chemicals and preservatives.
Number of Levels	3	2

Differences		
	Predicate Device	New product
	Fujirebio Diagnositics, Inc.'s Vitamin D Control	Complete D 25-OH Vitamin D Control
Volume	2.0mLs (reconstituted)	3mLs.
Storage (unopened)	12 months at 2 to 8° C	24 months at 2 to 8° C
Form	Lyophylized	Liquid

Technological Characteristics Compared to Predicate Devices (as required per Title 21 Sec 807.92).

The Quantimetrix control product employs a similar human serum matrix and constituent formulation to the equivalent predicate device listed above. The serum matrix is fortified with reagent grade chemicals as well as preservatives. The Quantimetrix Control also has similar storage and stability requirements as the equivalent device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Quantimetrix Corp.
c/o Kalyna Snylyk
2005 Manhattan Beach Blvd
Redondo Beach, CA 90278-1205

MAY 10 2012

Re: k113177
Trade Name: Quantimetrix Complete D 25-OH Vitamin D Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: April 19, 2012
Received: April 23, 2012

Dear Kalyna Snylyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form.

510(k) Number (if known): ____k113177_____

Device Name: Complete D® 25-OH Vitamin D Control

Indications for Use:

The Quantimetrix Complete D® 25-OH Vitamin D Control is intended for the quality control of laboratory procedures used to quantitate Total 25-OH Vitamin D.

Prescription Use _X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k113177